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IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

JOYCE OSHODI, individually and as mother and next friend of KENNETH OSHODI, a minor,

Respondents.

SMITHS INDUSTRIES MEDICAL SYSTEMS, INC.,

Petitioner,

v.

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,

Respondents.

On Petition for Writ of Certiorari to the Appellate Court of Illinois, First District

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Should this Court resolve the growing conflict among State and Federal Courts regarding the preemptive effect of the Medical Device Amendments on state law claims that challenge the safety and effectiveness of Class III medical devices approved by the United States Food and Drug Administration pursuant to the premarket approval process and/or the investigational device exemption process?

2. Do the Medical Device Amendments preempt state law claims that challenge the safety and effectiveness of Class III medical devices approved by the United States Food and Drug Administration pursuant to the premarket approval process and/or the investigational device exemption process?

RULE 29.6 STATEMENT

Petitioner, Smiths Industries Medical Systems, Inc., is a wholly-owned subsidiary of Smiths Industries, Inc. Smiths Industries, Inc. is a wholly-owned subsidiary of Smiths Industries plc.

Petitioner, Smiths Industries Medical Systems, Inc., has no nonwholly-owned subsidiaries.

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PETITION FOR WRIT OF CERTIORARI

Petitioner, Smiths Industries Medical Systems, Inc. ("SIMS"), respectfully petitions for a writ of certiorari to review the judgment of the Appellate Court of Illinois, First District.

OPINIONS BELOW

The opinion of the Appellate Court of Illinois is reported at 283 Ill. App. 3d 455, 669 N.E.2d 1300 (1st Dist. 1996). (App. at 1-19). The trial court rulings are unreported. (App. at 25, 26-31, 32).

JURISDICTIONAL STATEMENT

The Appellate Court of Illinois, First District, entered judgment on September 6, 1996. (App. at 1-19).

The Supreme Court of Illinois denied SIMS' Petition for Leave to Appeal on December 4, 1996. (App. at 20-24).

Jurisdiction of this Court arises under 28 U.S.C. §1257. In addition, review on Writ of Certiorari is warranted under Supreme Court Rule 10(b) because the Illinois Appellate Court decided an important Federal question in a way that conflicts with the decision of a United States Court of Appeals *and* another State court of last resort.

STATUTE INVOLVED

This case involves §360k(a) of the Medical Device Amendments of 1976, which provides as follows:

> (a) Except as provided in subsection (b) of this Section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a) (Supp. 1992).

STATEMENT OF THE CASE

I. PROCEEDINGS BELOW

A. In The Trial Court

This Petition arises from three separate products liability actions filed against SIMS in the Circuit Court of Cook County, Illinois: *Kernats v. SIMS; Oshodi v. SIMS;* and *Williams v. SIMS*.

The allegations and undisputed facts of all three cases are nearly identical. The plaintiffs in each case consist of a mother and a child allegedly born with limb deformities. In each case, the mother underwent chorionic villus sampling ("CVS") during her pregnancy. CVS is a medical procedure performed during the first trimester of

pregnancy to obtain a sample of fetal tissue which is then analyzed for genetic abnormalities.

The plaintiffs in each case allege that SIMS manufactured and sold the CVS catheter used in the CVS procedure in controversy. The plaintiffs further allege that the CVS procedure caused the then-unborn child to be born with limb deformities. The plaintiffs seek recovery under theories of strict products liability, common law negligence, and breach of express and implied warranties.

The CVS catheter involved in all three cases is classified as a "Class III" medical device under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§360c-360*l*. The MDA contains a comprehensive regulatory scheme which governs the development, marketing and distribution of all Class III medical devices. Pursuant to the MDA's regulatory scheme, certain Class III medical devices may be distributed for use only if the United States Food and Drug Administration ("FDA") grants the device (1) an Investigational Device Exemption ("IDE"), or (2) premarket approval ("PMA"). The FDA may grant a medical device an IDE or PMA only after carefully evaluating the device to ensure that it is safe and effective for its intended use. 21 C.F.R. §812.30, 21 U.S.C. §360e(d)(2).

On September 19, 1984, the FDA granted SIMS an IDE for the CVS catheter in controversy. That IDE was in effect when the CVS procedures at issue in *Oshodi* and *Williams* were performed on June 11, 1986, and October 12, 1988, respectively.

On August 9, 1990, the FDA granted SIMS premarket approval for the CVS catheter in controversy. On August

17, 1990, the FDA granted SIMS premarket approval for the warning label for the CVS catheter. The FDA's premarket approval of the CVS catheter and its warning label was in effect when the CVS procedure at issue in *Kernats* was performed (November 1, 1990) and has remained in effect through the present day.

In all three cases, SIMS moved for summary judgment on the grounds that all of the plaintiffs' claims were preempted by the express preemption provision of the MDA, 21 U.S.C. §360k(a).[1] The trial court granted SIMS' Motion for Summary Judgment in *Kernats* on November 17, 1994. (App. at 25). The trial court granted SIMS' Motion for Summary Judgment in *Oshodi* on June 22, 1995. (App. at 26-31). The trial court granted SIMS' Motion for Summary Judgment in *Williams* on June 30, 1995. (App. at 32).

B. In The Appellate Court of Illinois

The plaintiffs in all three cases appealed, and the Appellate Court consolidated the appeals based on their common facts and legal issues. On September 6, 1996, the Appellate Court reversed the judgment of the trial court in all three cases, holding that the MDA does not preempt any of the plaintiffs' claims. (App. at 1-19). The Appellate Court's decision (hereinafter "the *Kernats* decision") is reported at 283 Ill.App.3d 455, 669 N.E.2d 1300 (1st Dist. 1996).

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[1] Each of the three lawsuits was pending before a different trial court judge. All three trial judges granted SIMS' summary judgment motion.

C. Before the Supreme Court of Illinois

On October 8, 1996, SIMS timely filed a Petition for Leave to Appeal with the Supreme Court of Illinois. SIMS' Petition was denied on December 4, 1996. (App. at 20-24).

II. JUDGMENT SOUGHT TO BE REVIEWED

The Appellate Court in *Kernats* based its decision on this Court's decision in *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240 (1996). The plaintiff in *Medtronic* filed a products liability action against the manufacturer of an allegedly defective pacemaker lead. The pacemaker lead at issue in *Medtronic* was a Class III medical device. *Id.* at 2248. However, unlike the CVS catheter involved in this Petition, the pacemaker lead in *Medtronic* did *not* undergo the rigorous IDE or PMA regulatory process. *Id.* Rather, the pacemaker lead was marketed as a "substantially equivalent" medical device pursuant to the MDA's Premarket Notification process (hereinafter "the 510(k) process"). *Id.*

As will be explained in detail below, the 510(k) process subjects "substantially equivalent" Class III medical devices to only minimal review by the FDA (as compared to the rigorous IDE and PMA processes). Further, the FDA does *not* evaluate "substantially equivalent" devices for the purpose of ensuring their safety or effectiveness.

Despite the significant differences between the 510(k) process at issue in *Medtronic* and the IDE and PMA processes at issue in *Kernats*, the Appellate Court held that *Medtronic* compelled a finding that *none* of the plaintiffs' claims in *Kernats* is preempted. Specifically,

the Appellate Court held that the plaintiffs' strict liability, negligence, and breach of implied warranty claims are not preempted because those claims are based on "general obligations" applicable to all product manufacturers. (App. at 14-16). The Appellate Court further held that the plaintiffs' breach of express warranty claims are not preempted because those claims are not "imposed under State law", but rather are imposed by virtue of SIMS' own representations. (App. at 18).

REASONS FOR GRANTING THE WRIT

I.

BY GRANTING SIMS' WRIT, THIS COURT CAN CONCLUSIVELY RESOLVE THE GROWING CONFLICT THAT HAS ARISEN AMONG STATE AND FEDERAL COURTS IN CASES INVOLVING CLASS III MEDICAL DEVICES GRANTED INVESTIGATIONAL DEVICE EXEMPTIONS AND PREMARKET APPROVAL.

SIMS' Petition for Writ of Certiorari offers this Court the opportunity to resolve in *one decision* the two critical issues of MDA preemption that were not addressed in *Medtronic v. Lohr*.

A. *Medtronic v. Lohr* did not define the preemptive effect of the MDA in cases involving IDE and PMA Class III medical devices.

This Court's decision in *Medtronic* squarely addressed the scope of MDA preemption as it relates to "substantially equivalent" Class III medical devices marketed pursuant to the 510(k) process. Relying on this Court's decision in *Medtronic*, recent decisions involving 510(k) devices have reached consistent results, holding that the

MDA does not preempt state law causes of action brought against the manufacturers of such devices. See, *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. Dec. 18, 1996); *Dutton v. Acromed Corp.*, 1997 WL 15248 (Ohio App. Ct. January 16, 1997); *Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. January 20, 1997).

However, this Court's decision in *Medtronic* did not address the preemptive effect of the MDA as it relates to IDE and PMA Class III devices. For the purposes of MDA preemption, the differences between the 510(k) process and the IDE and PMA processes are significant.[2] As a result of those differences, the lower courts—including the Illinois Appellate Court in *Kernats*—have reached conflicting results in their attempts to apply the *Medtronic* decision to cases involving IDE and PMA Class III devices.

B. In the wake of *Medtronic*, State and Federal Courts have reached conflicting results in cases involving IDE and PMA Class III devices.

As stated previously, the *Kernats* decision was a consolidated appeal involving three separate lawsuits: *Kernats*, *Oshodi* and *Williams*. At the time the CVS procedure was performed on the Plaintiffs in *Oshodi* and *Williams*, the CVS catheter had been granted an IDE. At the time the CVS procedure was performed on the Plaintiff in *Kernats*, the CVS catheter had been granted PMA.

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[2] The differences between the 510(k) process and the IDE and PMA processes will be discussed in the following section of this petition.

Thus, the *Kernats* consolidated appeal (which is the subject of this Petition) involved questions regarding the preemptive effect of the MDA on (1) a Class III device granted an IDE, *and* (2) a Class III device granted PMA. The Illinois Appellate Court resolved those questions by holding that the plaintiffs' claims in all three underlying lawsuits survived preemption.

1) Conflicts in cases involving IDE Class III devices.

The *Kernats* decision—as it relates to IDE Class III devices—directly conflicts with the recent decision of the United States Court of Appeals for the Sixth Circuit in *Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1997 WL 35041 (6th Cir. January 31 1997).[3] *Martin* involved a Class III pacemaker that had been granted an IDE by the FDA. 1997 WL 35041 at *8. As in *Kernats*, the plaintiffs' claims against the defendant-manufacturer in *Martin* were based on defective manufacturing, defective design, inadequate warnings and breach of warranties. *Id.* at *1.

In direct conflict with the Illinois Appellate Court's decision in *Kernats*, the Sixth Circuit in *Martin* (1) distinguished *Medtronic* based on the differences between the 510(k) process and the IDE process, and (2) held that *all* of the plaintiffs' claims were preempted.

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[3] The conflict between the Illinois Appellate Court in *Kernats* and the Sixth Circuit in *Martin* brings the *Kernats* decision within this Court's jurisdiction on Writ of Certiorari under United States Supreme Court Rule 10(b).

The Sixth Circuit's decision in *Martin* also creates *another* conflict between a United States Court of Appeals and a State Court of last resort. S.Ct. Rule 10(b). The Sixth Circuit's decision in *Martin* directly conflicts with the decision of the Supreme Court of Missouri in *Connelly v. Iolab Corporation*, 927 S.W.2d 848, 853-54 (Mo. 1996) (holding that, pursuant to *Medtronic*, the MDA does not preempt claims based on negligence, strict liability, and failure to warn in a case involving IDE Class III device).

2) Conflicts in cases involving PMA Class III devices.

The *Kernats* decision—as it relates to PMA Class III devices—directly conflicts with the decision of the Supreme Court of Pennsylvania in *Green v. Dolsky*, 685 A.2d 110 (Pa. November 22, 1996).[4] *Green* involved a Class III cosmetic implant device that had been granted PMA by the FDA. *Id.* at 113,17. The plaintiff asserted numerous claims based on negligence, strict products liability, and breach of warranty. *Id.* at 117-18. The court in *Green* held that this Court's decision in *Medtronic* provided "some guidance", but *further held that Medtronic was "not wholly applicable" because of the differences between the PMA process and the 510(k) process. Id.* at 117.

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[4] The conflict between the Illinois Appellate Court in *Kernats* and the Pennsylvania Supreme Court in *Green also* brings the *Kernats* decision within this Court's jurisdiction on Writ of Certiorari under United States Supreme Court Rule 10(b).

In direct conflict with the Illinois Appellate Court in *Kernats*, the court in *Green* held that the MDA preempted the plaintiff's strict products liability, negligence[5], and breach of warranty claims. *Id.* at 117-18.

The decision of the Supreme Court of Pennsylvania in *Green* also conflicts with *Armstrong v. Optical Radiation Corporation*, 57 Cal.Rptr.2d 763 (Cal. Ct. App. October 29, 1996), and *Walker v. Johnson & Johnson Vision Products, Inc.*, 217 Mich. App. 705 (July 26, 1996), both of which held that MDA preemption does not apply to claims brought against manufacturers of Class III PMA devices.

C. Unless this Court renders a conclusive decision, the lower courts will continue to enter conflicting judgments regarding MDA preemption.

Absent a conclusive decision from this Court, the lower courts will continue to enter conflicting judgments in cases involving PMA and IDE Class III devices. As a result, this Court will continue to receive petitions for writs of certiorari in such cases.

The instant Petition submitted to this Court by SIMS is unique. Because this Petition involves questions regarding PMA *and* IDE Class III devices, this Court has the opportunity to conclusively resolve in one decision all remaining aspects of MDA preemption not addressed in *Medtronic v. Lohr*. For that reason, this Court should grant the instant Petition.

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[5] The court held that preemption did not apply to certain of the plaintiff's negligence claims which simply "mirrored" the federal requirements of the PMA process.

II.

OVERVIEW OF THE MEDICAL DEVICE AMENDMENTS OF 1976.

An overview of the MDA, as well as the different regulatory processes applicable to Class III medical devices, is crucial to an understanding of why the lower courts have been unable to consistently apply *Medtronic* to cases involving IDE and PMA Class III devices.

A. Classification of Medical Devices Under the MDA

Pursuant to the MDA, the FDA groups all medical devices into three classifications based on the degree of regulation necessary to assure the safety and effectiveness of each device. See 21 U.S.C. §360c; H.R. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 55 (1976), reprinted in 1976 U.S.C.C.A.N. 1103, 1107. Class I devices, such as crutches and tongue depressors, pose little or no threat to health and are subject only to general controls. 21 U.S.C. §360c(a)(1)(A). Class II devices, such as tampons and knee prostheses, involve a slightly greater risk to health and are subject to special controls such as performance standards and post-market surveillance. 21 U.S.C. §360c(a)(1)(B).

Class III devices, such as the CVS catheter in controversy, are those which present a "potential unreasonable risk of illness or injury" and therefore require the utmost scrutiny by the FDA. 21 U.S.C. §360c(a)(1)(C)(ii)(II). Class III medical devices may be distributed for use pursuant to three different regulatory schemes: (1) premarket approval, (2) investigational device exemptions, and (3) the 510(k) process.

B. Premarket Approval

The premarket approval process is the most exhaustive regulatory scheme imposed by the FDA under the MDA. To obtain premarket approval of a Class III device, the manufacturer or distributor of the device must submit a detailed application to the FDA. 21 U.S.C. § 360e(c)(1). The application must include (1) detailed reports of all investigations and studies concerning the safety and effectiveness of the device, (2) a full statement of the components, composition and principles of operation of the device, (3) a full description of the methods, facilities and controls used for the manufacture of the device, (4) samples of the device for examination and testing, and (5) copies of the proposed labeling for the device. 21 U.S.C. § 360e(c)(1).

The FDA refers each premarket approval application to an advisory panel of specially appointed independent scientists who then review the application and prepare a report and recommendation to the FDA. 21 U.S.C. §§ 360e(c)(2), 360c(b). The FDA may approve an application for premarket approval only if it determines that the device is reasonably safe and effective for its intended use. 21 U.S.C. § 360e(d)(2). A manufacturer or distributor is subject to criminal and civil penalties for marketing or selling a Class III medical device without first obtaining FDA premarket approval. 21 U.S.C. §§ 331(p), 333(a) (Supp. 1992).

Once a Class III medical device receives premarket approval, the FDA may withdraw the approval if it subsequently determines that the device is unsafe. 21 U.S.C. § 360e(e). To enable the FDA to monitor the safety of an approved device, the manufacturer or distributor

must maintain records and submit product safety reports to the FDA. 21 U.S.C. § 360i(a)(1). A manufacturer or distributor is subject to criminal and civil penalties for failing to comply with these continuous reporting and record-keeping requirements. 21 U.S.C. §§ 331(e), 333(a) (Supp. 1992).

C. Investigational Device Exemptions

In enacting the MDA, Congress recognized that certain experimental Class III medical devices cannot be proven safe and effective—and therefore obtain premarket approval—without the benefit of preliminary clinical studies. Therefore, the MDA specifically provides for Investigational Device Exemptions ("IDEs"). 21 U.S.C. §§ 360e(a), 360j(g). IDEs permit qualified experts to investigate the safety and effectiveness of Class III devices by conducting clinical tests on human subjects before such devices have received premarket approval. 21 U.S.C. §§ 360e(a), 360j(g). Congress announced the purpose of IDEs as follows:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1).

Although Class III devices receiving IDEs are exempt from the premarket approval process, such devices are nonetheless subject to extensive regulatory requirements promulgated and enforced by the FDA. 21 U.S.C.

§ 360j(g)(3); 21 C.F.R. §§ 812.1-150. To obtain an IDE, the sponsor of a proposed clinical investigation must complete a detailed application containing (1) a description of the device specifying its design as well as the methods, controls and facilities used for its manufacture; (2) copies of all labeling for the device; (3) the proposed plan for investigating the use of the device in human subjects; (4) written procedures for monitoring the investigation; and (5) complete reports of all prior investigations of the device. 21 U.S.C. §§ 360j(g)(2)-(3); 21 C.F.R. §§ 812.20-27.

The FDA and an institutional review committee must then review the application. 21 U.S.C. § 360j(g)(3)(a); 21 C.F.R. §§ 812.42. The FDA must reject the application if it determines there is reason to believe the investigation is scientifically unsound, the risks outweigh the anticipated benefits, or the device is ineffective. 21 C.F.R. § 812.30.

If the FDA grants a medical device an IDE, the sponsor must continuously monitor the investigation, maintain records and provide the FDA with reports describing the results of the investigation. 21 U.S.C. § 360j(g)(2)(B)(ii); 21 C.F.R. §§ 812.46; 812.140; 812.150. In addition, the sponsor must allow the FDA to inspect the investigation and manufacturing facilities and all records pertaining to the investigation. 21 C.F.R. § 812.46. The FDA must withdraw an IDE if it determines that a continuation of the clinical investigation will result in an unreasonable risk to the public health. 21 U.S.C. § 360j(g)(5). Any person who fails to comply with the requirements applicable to IDEs is subject to substantial criminal and civil penalties. 21 U.S.C. § 331(q)(1), § 333(a) (Supp. 1992).

D. The 510(k) Process

As this Court explained in *Medtronic*, a Class III medical device may bypass the IDE and PMA processes if the FDA determines that the device is "substantially equivalent" to a medical device marketed before the MDA became effective in 1976. 116 S.Ct. at 2247. A manufacturer of a Class III device may seek a finding of substantial equivalence from the FDA by participating in the 510(k) Notification Process. *Id.*

In *Medtronic*, this Court repeatedly emphasized the cursory nature of the 510(k) process. This Court explained that the 510(k) process is completed in an average of only 20 hours (as opposed to the 1,200 hours ordinarily involved in the PMA process). *Id.* This Court also emphasized that "the 510(k) process is focused on equivalence, not safety." *Id.* at 2254. In that regard, the Court quoted one commentator as follows:

> Substantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.

Id. (quoting Adler, 43 Food Drug Cosm. A.J., at 516). Elaborating further, this Court observed that the only requirements imposed under the 510(k) process constitute—

> Entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to pro-

tect from potentially contradictory state requirements.

Id. at 2258.

III.

THIS COURT BASED ITS FINDING OF NO PREEMPTION IN *MEDTRONIC* ON THE NATURE AND PURPOSE OF THE 510(K) PROCESS.

The MDA's express preemption provision, 21 U.S.C. §360k(a), provides as follows:

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (Supp. 1992).

In *Medtronic*, this Court held that preemption occurs only when a medical device is subject to "specific" federal requirements. 116 S.Ct. at 2257. This Court also held that preemption applies only to state law requirements developed "with respect to" medical devices, as opposed to state requirements of "general applicability". *Id.* However, this Court acknowledged that "general" state requirements are not necessarily excluded from the scope of preemption. *Id.* Rather, preemption will occur when a

"general" state requirement "threatens to interfere with a specific federal interest". *Id.*

Based upon the foregoing guidelines for preemption, this court held that the plaintiffs' claims in *Medtronic* were not preempted for two reasons. First, the 510(k) process at issue in *Medtronic* did not impose "specific" federal requirements on the pacemaker lead in controversy. *Id.* at 2258. Second, this Court held that the plaintiffs' claims of negligence and strict products liability constituted "general" state law requirements which—

> are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. *Id.*

Critical to this Court's decision in *Medtronic* was its discussion of the underlying purpose of the 510(k) process. This Court explained that by permitting the manufacturers of "substantially equivalent" devices to bypass the PMA process, Congress intended merely to enable those manufacturers to compete on an equal basis with the manufacturers of medical devices that existed before the MDA was enacted. *Id.* at 2254. In that regard, this Court held as follows:

> There is no suggestion in either the statutory scheme or the legislative history that the 510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state law claims of negligent design.

Id. at 2254-55. Since Congress did not intend to afford "substantially equivalent" device manufacturers preferential treatment, this Court held that the imposition of state law claims such as those asserted by the plaintiffs in *Medtronic* did not threaten the specific federal interest underlying the 510(k) process. *Id.*

IV.

THE PREEMPTION ANALYSIS ESTABLISHED IN *MEDTRONIC* COMPELS A FINDING IN FAVOR OF PREEMPTION IN CASES INVOLVING IDE AND PMA CLASS III MEDICAL DEVICES.

Although this Court ruled against preemption in *Medtronic*, the preemption analysis established in that case strongly suggests that a different result is warranted in cases involving IDE and PMA Class III devices.

A. The comprehensive and detailed nature of the IDE and PMA processes militate in favor of preemption.

As demonstrated earlier in this Petition, the IDE and PMA processes (as opposed to the 510(k) process) involve a comprehensive array of "specific" federal requirements. In cases decided before and after *Medtronic*, including the *Kernats* decision at issue in this Petition, the courts have consistently held that the requirements of the IDE and PMA processes are sufficiently specific to trigger preemption. See, e.g., *Kernats v. Smiths Industries Medical Systems, Inc.*, 283 Ill.App.3d 455, 669 N.E.2d 1300, 1308 (1st Dist. 1996) (PMA requirements sufficiently specific); *Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1997 WL 35041 (6th Cir. January 31

1997) (IDE requirements sufficiently specific); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir. 1993) (PMA requirements sufficiently specific); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992) (IDE requirements sufficiently specific). Thus, the requirements of the IDE and PMA processes, unlike the "generic" requirements of the 510(k) process, are sufficiently specific to satisfy the *Medtronic* preemption guidelines.

B. The Congressional goals underlying the IDE and PMA processes require that such devices be afforded the protection of MDA preemption.

The Congressional purposes of the IDE and PMA processes also differ dramatically from the purpose of the 510(k) process. Congress announced the purpose of IDEs as follows:

> It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). Similarly, the PMA process is intended to ensure the safety and effectiveness of medical devices designed "for a use in sustaining human life or for a use which is of substantial importance in preventing impairment of human health". 21 U.S.C. §360c(a)(1)(C).

Unlike the 510(k) process, the IDE and PMA processes are not intended merely to facilitate the marketing of "substantially equivalent" devices that duplicate the

benefits of devices already in existence. To the contrary, Congress enacted the IDE and PMA processes to encourage the development of innovative, substantially important medical devices, and to provide the FDA with the authority and means to evaluate the safety and effectiveness of such devices. As set forth below, the preemption of state tort law claims is crucial to the achievement of those congressional objectives.

Without question, the threat of widespread tort litigation constitutes a formidable deterrent to the development of innovative, potentially life-saving medical devices. In 1988 a report of the American Medical Association ("AMA") Board of Trustees concluded that "[p]roduct liability is having a profound negative impact on the development of new medical technologies."[6] The AMA report explained that "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance".[7]

The threat of widespread tort litigation has a particularly chilling effect on smaller manufacturers which, although often responsible for developing the most innovative medical devices, have less financial resources at their disposal. Absent any protection from MDA preemption, such smaller manufacturers will be compelled to cease the development of potentially life-saving medical devices—or withdraw such devices from the market—rather than face the threat of devastating litigation

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[6] AMA, Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies 1 (June 1988).

[7] *Id.*

defense costs. Such a result will severely undermine Congress' goal of promoting the advancement of medical device technology, and will also jeopardize the interests of countless patients whose very lives may depend on the continued availability of innovative medical devices.

The CVS catheter at issue in this Petition demonstrates the kind of significant social value innovative IDE and PMA Class III devices may offer. CVS enables physicians to perform prenatal genetic testing at an earlier stage than pre-existing procedures such as amniocentesis. The early diagnosis of fetal abnormalities attainable through CVS aids the decision making process of parents and may enable physicians to correct such abnormalities. CVS has been performed safely on thousands of patients[8], and criticisms of the procedure have largely focused on the timing of the procedure rather than the design of the SIMS catheter. Nonetheless, absent MDA preemption, SIMS and similar medical device manufacturers, despite having received FDA approval, must defend themselves in litigation such as the underlying lawsuits.

In *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992), a case involving an IDE Class III device, the United States Court of Appeals for the Seventh Circuit explicitly recognized the chilling effect tort liability may have on the advancement of medical device technology. There, the Seventh Circuit held in relevant part as follows:

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[8] Jackson, et al., A Randomized Comparison of Transcervical and Transabdominal Chorionic Villus Sampling, New England Journal of Medicine, Vol. 327, No. 9 at 594.

> If experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.

Id. at 1334. In furtherance of Congress' goal to promote the advancement of medical device technology, the Seventh Circuit in *Slater* held that the MDA preempted all of the state law tort claims the plaintiff had brought against the manufacturer of an IDE Class III device. *Id.* at 1334.

More recently, in *Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1997 WL 35041 (6th Cir. January 31 1997), the United States Court of Appeals for the Sixth Circuit held that the structure and purpose of the IDE process *demands* the preemption of state tort law claims. *Martin* involved a Class III pacemaker that had been granted an IDE by the FDA. *Id.* at *8. The court in *Martin* noted that IDE devices (1) are subject to a specific set of "comprehensive regulations which set forth detailed procedures for determining whether investigational devices are safe and effective," and (2) are expressly *exempted* from the "performance standards" and "good manufacturing practices" normally applicable to other, non-investigational devices. *Id.* at *5-6.

Turning to the plaintiffs' claim for defective manufacturing, the court held as follows:

> The purpose of the exemption for investigational devices is to promote safety and innovation, the twin aims of the investigational device exemption of the MDA. *To allow a cause of action for a manufacturing defect under state law where the FDA has specifically exempted an investigational*

> *device from Good Manufacturing regulations would thwart the goals of the IDE exemption "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use."* 21 U.S.C. § 360j(g). We, therefore, hold that the Martins' manufacturing defect cause of action is preempted.

Id. at *9 (emphasis added). With respect to the plaintiffs' defective design claim, the court held as follows:

> To allow a cause of action for design defect where the FDA has specifically approved of the design of the device for investigational purposes would thwart the goals of safety and innovation. Accordingly, Count II of Plaintiffs' complaint is similarly preempted.

Id. at *10.

As the Sixth Circuit recognized in *Martin*, in order to "maintain optimum freedom for scientific investigators", 21 U.S.C. § 360j(g)(1), the IDE process exempts investigational devices from those federal requirements ordinarily applicable to all other devices. By permitting *state* requirements to stand where even *federal* requirements are prohibited, the allowance of state law tort claims against investigational devices totally conflicts with the structure of the IDE process, and seriously threatens the freedom of device manufacturers to pursue the development of potentially life-saving medical devices. Similarly, by allowing juries to second-guess the FDA and evaluate the safety and effectiveness of devices *already deemed safe and effective by the FDA*, state tort law claims directly undermine the federal interest in entrusting

such evaluations to the FDA. For those reasons, such claims should not be allowed to survive preemption.

V.

ADDITIONAL CONSIDERATIONS UNDERLYING THIS COURT'S DECISION IN *MEDTRONIC* STRONGLY SUGGEST THAT PREEMPTION IS WARRANTED IN CASES INVOLVING IDE AND PMA CLASS III MEDICAL DEVICES.

A. Unlike "substantially equivalent" Class III medical devices, IDE and PMA Class III medical devices are comprehensively examined by the FDA to ensure their safety and effectiveness, and comprise only a small percentage of all medical devices distributed to the public.

This Court repeatedly emphasized in *Medtronic* that "substantially equivalent" Class III devices marketed pursuant to the 510(k) process are not evaluated for safety or effectiveness. This court observed that "the 510(k) process is focused on equivalence, not safety." 116 S.Ct. at 2254. This Court also noted that the 510(k) process "requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Id.* at 2247. Finally, this Court explained that the 510(k) review process is completed in an average of *only 20 hours. Id.*

In *Medtronic*, this Court also explained that the vast majority of Class III medical devices introduced after 1976 have been marketed pursuant to the 510(k) process. This Court noted that a 1983 House Report "concluded that nearly 1,000 of approximately 1,100 Class III devices that had been introduced to the market since 1976 were admitted as substantial equivalents and without

any PMA review." 116 S.Ct. at 2247. This Court also cited a 1990 House Report that showed that 80% of new Class III devices were being introduced to the market through the 510(k) process and without PMA review. *Id.* at 2248.

The foregoing considerations undoubtedly played a significant role in this Court's finding of no preemption in *Medtronic*. A contrary holding in favor of preemption would have provided total immunity to the manufacturers of Class III medical devices that have never been specifically reviewed for safety or effectiveness. The error of such a result would have been compounded by (1) the sheer number of Class III medical devices introduced to market through the 510(k) process, and (2) the fact that Class III medical devices, by definition, are those which present a "potential unreasonable risk of illness or injury". 21 U.S.C. §360c(a)(1)(C)(ii)(II). Thus, for obvious reasons, the Supreme Court preserved common law tort remedies with respect to a particularly large subclass of potentially dangerous, minimally regulated, medical devices.

The considerations that disfavored preemption in *Medtronic* do not apply to cases involving IDE and PMA Class III medical devices. As demonstrated above, IDE and PMA Class III devices are comprehensively examined by the FDA to ensure their safety and effectiveness. In fact, this Court in *Medtronic* highlighted the fact that the FDA devotes an average of 1,200 hours to each PMA application (as opposed to the mere 20 hours involved in the 510(k) process). *Id.* at 2247. The IDE process involves the same kind of rigorous FDA review. Furthermore, in contrast to 510(k) devices, IDE and PMA Class

III devices comprise a small fraction of the total medical devices distributed to the public.

Thus, unlike a finding of preemption with respect to 510(k) devices, a finding of preemption with respect to IDE and PMA Class III devices would apply only to a small number of intensely regulated medical devices.

B. In *Medtronic*, a majority of this Court's Justices held that the MDA will preempt state law tort claims under appropriate circumstances.

In *Medtronic*, Justice Stevens wrote that "few, if any, common-law duties have been pre-empted by" the MDA. 116 S.Ct. at 2259. A majority of Justices, however, disagreed with that conclusion. Justice Breyer specifically declined to join that aspect of Justice Stevens' opinion, holding that "I am not convinced that future incidents of MDA pre-emption of common-law duties will be 'few' or 'rare'". *Id.* at 2262. In addition, Justice O'Connor (joined by Justices Rehnquist, Scalia and Thomas) expressly concluded that common-law claims are subject to pre-emption by the MDA. *Id.* at 2263.

Thus, the critical—yet unanswered—question involves the circumstances under which the MDA will preempt common-law tort claims such as those at issue in this Petition. The answer must be that preemption is appropriate in cases involving IDE and PMA Class III devices. No other devices are subject to the same degree of specific federal requirements relating to safety and effectiveness. No other devices are subject to a regulatory scheme specifically intended to promote the advancements of medical device technology. In short, no other devices are

more deserving of the protection afforded by the MDA's express preemption provision.

For those reasons, this Court's decision in *Medtronic* appears to lead to the inescapable conclusion that MDA preemption applies to common-law claims that challenge the safety and effectiveness of IDE and PMA Class III devices.

In conclusion, several aspects of this Court's decision *Medtronic* strongly suggest that the MDA preemption should be invoked in cases involving IDE and PMA Class III devices. As a result, courts such as the Sixth Circuit in *Martin v. Telectronics* and the Pennsylvania Supreme Court in *Green v. Dolsky* have held in favor of preemption. However, due to the perceived uncertainties regarding this Court's decision in *Medtronic*, other courts such as the Illinois Appellate Court in *Kernats* and the Missouri Supreme Court in *Connelly v. Iolab* have held against preemption.

There is no reason to believe that the growing conflict among the lower courts will resolve itself. The intervention of this Court is the only feasible solution. By accepting the instant Petition, this Court can conclusively resolve *in one decision* the critically important issues regarding MDA preemption as it relates to IDE Class III devices and PMA Class III devices. SIMS' petition for writ of certiorari should be granted.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

No. 94-4386 (Consolidated with 95-3128 and 95-3129)

IN THE APPELLATE COURT OF ILLINOIS
FIRST JUDICIAL DISTRICT—SECOND DIVISION

SARAH KERNATS, et al., Plaintiffs-Appellants, v. SMITHS INDUSTRIES MEDICAL SYSTEMS, INC., Defendant-Appellee.	)	On Appeal from the Circuit Court of Cook County, Law Division No. 91 L 13573 Honorable Joseph N. Casciato, Judge Presiding
JOYCE OSHODI, et al., Plaintiffs-Appellants, v. SMITHS INDUSTRIES MEDICAL SYSTEMS, INC., Defendant-Appellee.	)	On Appeal from the Circuit Court of Cook County, Law Division No. 94 L 7177 Honorable Robert V. Boharic, Judge Presiding
MARY SUSAN WILLIAMS, et al., Plaintiffs-Appellants, v. SMITHS INDUSTRIES MEDICAL SYSTEMS, INC., Defendant-Appellee.	)	On Appeal from the Circuit Court of Cook County, Law Division No. 93 L 015781 Honorable Jennifer Duncan-Brice, Judge Presiding

Decided September 3, 1996

Presiding Justice HARTMAN delivered the opinion of the court:

This action involves three consolidated appeals. Plaintiffs in all three cases filed suit against defendant Smith Industries Medical Systems, Inc., d/b/a Concord/Portex, Inc., to recover damages for injuries allegedly caused by a medical product that it manufactured, distributed, and sold. In all cases, the circuit court entered summary judgment in favor of defendant on the ground that plaintiffs' claims were preempted by the Medical Device Amendments of 1976 (the "MDA") (21 U.S.C. §§ 360c-3601 (1988)) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-395 (1988)). Plaintiffs in all three cases appeal those judgments.[1]

Following oral argument in this appeal, the parties successfully moved that this court await the ruling of the United States Supreme Court in *Medtronic, Inc. v. Lohr,* 518 U.S. ___, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (*Medtronic*), which involved issues similar to those presented in this case: whether plaintiffs' state law tort claims are preempted by the MDA.

The allegations and undisputed facts in all three cases are essentially the same. In each case, the mother underwent chorionic villus sampling ("CVS") during her pregnancy. CVS is a medical procedure performed during

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[1] Plaintiff Mary Susan Williams, as mother and next friend of John Calvin Williams, a minor, also appealed from orders dismissing defendants Illinois Masonic Medical Center and Alan Cadkin, M.D. On January 31, 1996, this court entered an order allowing the partial dismissal of these defendants because the issues in their appeal did not relate to the preemption question common to the other consolidated cases.

the first trimester of pregnancy to obtain a sample of fetal tissue which is subsequently analyzed by geneticists for genetic abnormalities. Defendant manufactured, distributed, and sold the CVS catheter used in each CVS procedure. Plaintiffs allege that the CVS procedure caused the minors to be born with limb abnormalities.

Plaintiffs in all three appeals asserted identical theories of liability: (1) strict products liability based on the allegedly defective design and manufacture of the CVS catheter, failure to warn, and inadequate instructions; (2) breach of express and implied warranties; and (3) common law negligence based on failure to warn, inadequate testing, and negligent design of the CVS catheter.[2]

The CVS catheters involved received Food and Drug Administration (FDA) premarket approval on August 9, 1990. The catheter is used in obtaining chorionic tissue samples making possible prenatal diagnosis of genetic abnormalities. 55 Fed.Reg. 42779 (1990). On August 17, 1990, the FDA granted defendant additional premarket approval for the warning label on the CVS catheter.

Defendant successfully moved for summary judgment in all three cases, based upon asserted MDA preemption of plaintiffs' state law claims. The circuit courts found no just reason to delay enforcement or appeal of the orders pursuant to Supreme Court Rule 304(a) (155 Ill.2d

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[2] Those provisions of the Civil Justice Reform Amendments of 1995 relating to product liability actions are inapplicable to this case because they apply only to causes of action filed on or after March 9, 1995. Pub.Act. 89-7, § 15, eff. March 9, 1995. Each of the three consolidated actions involved here was filed prior to the effective date of the amendments.

R.304(a)). Plaintiffs timely filed notices of appeal from those respective orders. We consolidated the cases for purposes of appeal.

I

Summary judgment properly may be entered if the pleadings, exhibits, affidavits and depositions on file disclose no genuine issue of material fact entitling the movant to judgment as a matter of law. *Dudek, Inc. v. Shred Pax Corp.*, 254 Ill.App.3d 862, 868, 193 Ill.Dec. 653, 626 N.E.2d 1204 (1993); *Bernard v. Sears, Roebuck & Co.*, 166 Ill.App.3d 533, 534, 116 Ill.Dec. 945, 519 N.E.2d 1160 (1988). The principal issue, that of preemption, is a question of law which will be examined under a de novo standard of review. *Zoeller v. Augustine*, 271 Ill.App.3d 370, 374, 208 Ill.Dec. 17, 648 N.E.2d 939 (1995); *American Health Care Providers, Inc. v. County of Cook*, 265 Ill.App.3d 919, 923, 202 Ill.Dec. 904, 638 N.E.2d 772 (1994).

The MDA comprehensively regulates medical devices. The FDA is authorized to classify medical devices intended for human use into three categories based on the degree of regulation necessary to assure safety and effectiveness. See 21 U.S.C. § 360c. See generally *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2246

Class I devices, such as tongue depressors, are subject only to general controls on manufacturing processes because they pose little threat to public health and safety. 21 U.S.C. § 360c(a)(1)(A); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1418 (5th Cir.1993). Class II devices, such as bone-conduction hearing aids, for which "general controls by themselves are insufficient to provide reasonable as-

surance of the safety and effectiveness of the device," are subject to special controls. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 874.3300 (1995). Class III devices, applying to the CVS catheter in this case, present "a potential unreasonable risk of illness or injury," and are subject to the most stringent MDA controls. 21 U.S.C. § 360c(a)(1)(C).

In order to market a Class III device, a manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2246, citing 21 U.S.C. § 360e(d)(2). This is accomplished by obtaining premarket approval (PMA), a rigorous process that requires manufacturers to submit to the FDA detailed information regarding the safety and efficacy of their medical devices. *Medtronic,* 518 U.S. at ___ - ___, 116 S.Ct. at 2246-47.

As part of the PMA application for a Class III device, a manufacturer must submit a bibliography of all reports concerning the device's safety and effectiveness, an outline of the device's components and properties, a description of the manufacturing process, safety data, samples of the device, copies of all proposed labeling, and any other information the FDA requests. 21 U.S.C. § 360e(c)(1). See also 21 C.F.R. § 814.20 (1995). The application is referred to a panel of qualified experts for study and submission of a report and recommendation respecting approval. 21 U.S.C. § 360e(c)(2). The FDA retains the right to withdraw its approval if it finds that a device previously approved is unsafe or ineffective. 21 U.S.C. § 360e(e).

Two important exceptions to the PMA requirement allow Class III devices to reach the marketplace without

PMA review. First, a grandfather provision allows pre-1976 medical devices to remain on the market until such time as the FDA initiates and completes the requisite PMA. See 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1995). Second, the MDA allows devices that are "substantially equivalent" to preexisting devices to avoid the PMA process in order to permit them to compete with grandfathered devices. See 21 U.S.C. § 360e(b)(1)(B). See generally *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247.

Manufacturers of "substantially equivalent" Class III devices must submit to a limited form of review known as "premarket notification" to the FDA (the process is also known as a "§ 510(k) process"), which allows the device to be marketed without further regulatory analysis if the FDA decides that it is "substantially equivalent" to a preexisting device. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247. The § 510(k) notification process is limited in scope when contrasted to the PMA process. Whereas the PMA process requires about 1,200 hours of review, the § 510(k) process is completed in an average of only 20 hours. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247. Section 510(k) notification requires little information and is seldom rejected by the FDA. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2247.[3] The PMA procedure was followed in the instant cases.

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[3] Another exception to the PMA process permits a Class III device that receives an "Investigational Device Exemption" (IDE) from the FDA to be tested on human subjects without obtaining PMA approval. 21 U.S.C. §§ 360e(a), 360j(g). In this case, the CVS catheter obtained an IDE from the FDA in September 1984, prior to defendant's submission of the PMA application.

II

The Constitution provides that the laws of the United States "shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI. State law that conflicts with Federal law is "without effect." *Maryland v. Louisiana,* 451 U.S. 725, 746, 101 S.Ct. 2114, 2129, 68 L.Ed.2d 576, 595 (1981). Nevertheless, when considering a preemption question, there is an assumption that a federal law will not supersede the historic police powers of states unless the purpose of Congress is clear and manifest. *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407, 422 (1992) (*Cipollone*); *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2250.

Congressional purpose is the "ultimate touchstone" in every preemption case. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2250, quoting *Retail Clerks International Association v. Schermerhorn,* 375 U.S. 96, 103, 84 S.Ct. 219, 222, 11 L.Ed.2d 179, 184 (1963). Congress' intent may be stated explicitly in the language of the statute or implicitly contained in its structure and purpose. *Cipollone,* 505 U.S. at 516, 112 S.Ct. at 2617, 120 L.Ed.2d at 422-23; *Medtronic,* 518 U.S. at ___ - ___, 116 S.Ct. at 2250-51. Absent an express congressional command, state law is pre-empted "if that law actually conflicts with federal law, [citation], or if federal law so thoroughly occupies a legislative field 'as to make reasonable the inference that Congress left no room for the States to supplement it. [Citation.]'" *Cipollone,* 505 U.S. at 516, 112 S.Ct. at 2617, 120 L.Ed.2d at 423.

Section 360k(a) of the MDA provides in pertinent part:

> "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

Although section 360k(a) expressly portends to preempt state law, it does so ambiguously. *Medtronic,* 518 U.S. at ___, ___, 116 S.Ct. at 2250, 2255.

In *Medtronic,* the Supreme Court noted that the scope of federal preemption under section 360k is ambiguous because the language of the statute "is not entirely clear." 518 U.S. at ___, 116 S.Ct. at 2255. This fact, coupled with the express congressional grant of authority to the FDA to implement the provisions of the MDA (see 21 U.S.C. § 360k(b)), rendered the FDA "uniquely qualified" to determine whether a particular form of state law conflicts with the MDA's objectives. *Medtronic,* 518 U.S. at ___ - ___, 116 S.Ct. at 2255-56. These considerations provided sufficient reason to give "substantial weight" to the FDA's construction of the statute. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2256.[4]

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[4] The dissenting justices in *Medtronic* concluded that it was improper to resort to the FDA's interpretation of section 360k because they believed the statute was clear. *Medtronic,* 518 U.S. at ___, 116 S.Ct. at 2263 (O'Connor, J., concurring in part and dissenting in part).

The *Medtronic* Court found the following FDA regulations most salient in resolving the preemption question. See *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257. "State * * * requirements are preempted only when the [FDA] has established specific counterpart regulations or * * * other specific requirements applicable to a particular device * * *." 21 C.F.R. § 808.1(d) (1995). Further, section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1) (1995). See also 21 C.F.R. § 808.1(d)(6)(ii) (1995).

The majority in *Medtronic* emphasized that the primary concern of the MDA was that preemption occur only where a "particular state requirement" threatened to interfere with a "specific federal interest." 518 U.S. at ___, 116 S.Ct. at 2257. The Supreme Court then essentially identified a two-pronged inquiry in this type of case. First, the "specific" federal requirements must be reviewed; if found "applicable to the device" in question, the requirements will preempt state law only if they are "specific counterpart regulations" or "specific" to a "particular device." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257.

Second, the "particular" state requirements must be examined. In order to be preempted, state requirements must, "with respect to" medical devices, be "different from, or in addition to" federal requirements, and relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the

device." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257. State requirements of "general applicability" are not preempted except where they have "the effect of establishing a substantive requirement for a specific device." 21 C.F.R. § 808.1(d)(6)(ii) (1995); *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257.

The Supreme Court cautioned that preemption analysis under the MDA "require[s] a careful comparison" between the assertedly preempting federal requirement and the allegedly preempted state requirement to determine whether they fall within the scope of the statute and regulations. *Medtronic*, 518 U.S. at ___ - ___, 116 S.Ct. at 2257-58.

The *Medtronic* Court was divided as to whether state common-law damages actions could ever be preempted by the MDA. A majority of the Court held that such actions do impose "requirements" under the MDA and are therefore preempted when the other conditions are satisfied. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2262 (O'Connor, J., concurring in part and dissenting in part).[5] The majority based this conclusion on its reading of *Cipollone*, in which the Supreme Court noted that "'[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. * * * [Citation.]'" 505 U.S. at 521, 112 S.Ct. at 2620, 120 L.Ed.2d at 426.

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[5] Justice Breyer agreed with the discussion of the four dissenting justices on this point. *Medtronic*, 518 U.S. at ___ - ___, 116 S.Ct. at 2259-60 (Breyer, J., concurring in part and concurring in the judgment). The plurality concluded that future incidents of MDA preemption of common-law claims would be "few" or "rare." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2259 (Stevens, J., plurality).

In *Medtronic*, the medical device in question was a pacemaker, a Class III device. The manufacturer of the pacemaker notified the FDA that it intended to market the pacemaker as a device that was "substantially equivalent" to products already on the market; it therefore took advantage of § 510(k)'s expedited review process and escaped PMA scrutiny. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2248. Plaintiff there was injured when her pacemaker failed. She and her husband sued the manufacturer under negligence and strict liability counts, alleging defective design and manufacture, failure to warn, and inadequate instructions. 518 U.S. at ___, 116 S.Ct. at 2248.[6] The manufacturer successfully moved for summary judgment, arguing that the tort claims were preempted by the MDA. The Federal district court dismissed plaintiffs' entire complaint, and the Court of Appeals reversed in part and affirmed in part. *Lohr v. Medtronic*, 56 F.3d 1335 (11th Cir.1995).

The Supreme Court held that none of plaintiffs' state law tort claims were preempted by the MDA. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2259. With respect to the defective design claims, the Court concluded that under the § 510(k) process, the pacemaker never had been formally reviewed for safety or efficacy; the focus of that procedure had been on equivalence, not safety. Because that process did not impose a federal "requirement," there was no preemption. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2254.

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[6] A third count alleging breach of warranty was dismissed for failure to state a claim under Florida state law. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2248.

Concerning plaintiffs' manufacturing and labeling claims, the manufacturer argued that the general federal regulations governing the labeling and manufacture of all medical devices were federal "requirements," sufficient to preempt plaintiff's claims. See 21 C.F.R. §§ 801.109, 820.20-820.198 (1995). The Supreme Court rejected that contention, observing that the federal labeling and manufacturing regulations "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns" contemplated by the preemption provision of the MDA. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258. In addition, the general state common-law requirements in the case were not specifically developed "with respect to" medical devices and were not "the kinds of requirements" that would impede the implementation and enforcement of specific federal requirements. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258. Accordingly, none of the claims based on defective manufacturing or labeling were preempted by the MDA.

III

In the case sub judice, defendant submitted an application to the FDA for approval of its CVS catheter pursuant to section 360e(c)(1) of the MDA. In August 1989, the Obstetrics and Gynecology Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. The FDA's Center for Devices and Radiological Health approved the application and notified defendant on August 9, 1990. See 55 Fed.Reg. 42779 (1990).

Defendant urges that the *Medtronic* decision is not controlling since the CVS catheter, unlike the pacemaker at issue in *Medtronic*, "ran the gauntlet" of PMA review and obtained FDA approval for its safety and effectiveness. We agree that the facts in the present case are different from those in *Medtronic* because the medical device here underwent rigorous PMA scrutiny. Yet, we are obliged to follow the analytical framework and guidance provided by the Supreme Court in that case.

One prong in the *Medtronic* analysis is whether there is a "specific" federal requirement "applicable to the device" at issue. Whether the PMA review process is sufficiently concrete to impose such a preempting federal requirement was not considered by the Supreme Court, but was addressed by several courts prior to that ruling. Most of those decisions hold that PMA review constitutes a specific federal "requirement" within the meaning of section 360k and regulation section 808.1(d). See, e.g., *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir.1994); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 & n. 3 (5th Cir.1993). But see *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-60 (9th Cir.1995).[7] We conclude, as have the majority of courts, that the PMA process is a specific federal requirement.

The second prong to be considered is whether the corresponding state requirement was "specifically developed

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[7] In the interpretation of a federal statute, the decisions of the federal courts are controlling on Illinois courts. *Golden Bear Family Restaurants, Inc. v. Murray*, 144 Ill.App.3d 616, 619-20, 98 Ill.Dec. 459, 494 N.E.2d 581 (1986); *Arnold v. Babcock & Wilcox Co.*, 154 Ill.App.3d 863, 870, 107 Ill.Dec. 554, 507 N.E.2d 218 (1987), *aff'd*, 123 Ill.2d 67, 121 Ill.Dec. 253, 525 N.E.2d 59 (1988).

'with respect to' medical devices." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258. The *Medtronic* Court held that common-law claims challenging the manufacturing and labeling of medical devices were not preempted by the MDA because they were simply "general obligations" imposed by the State on manufacturers; they were not state requirements specifically developed "with respect to" medical devices. 518 U.S. at ___, 116 S.Ct. at 2258.

Here, plaintiffs' common-law claims based on the manufacture of the CVS catheter, the failure to warn, and inadequate instructions, are also "general obligations" applicable to all manufacturers and, under the holding in *Medtronic*, are not requirements specifically established for medical devices. Therefore, they are not preempted under the MDA. Plaintiffs' claims based on defective design and inadequate testing allege that defendant defectively designed and failed to adequately test the CVS catheter. Although these allegations relate to the specific medical device at issue here, they arise, nevertheless, from general duties applicable to every manufacturer. The *Medtronic* Court explained:

> "The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the *general duty of every manufacturer to use due care to avoid foreseeable dangers in its products*. Similarly, the predicate for the failure to warn claim is the *general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use*. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. *These state requirements therefore*

> *escape pre-emption, not because the source of the duty is judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers.*" (Emphasis added.) *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2258.

Similarly here, plaintiffs' claims emanate from general common-law duties and are not the sort of state requirement that section 360k was intended to preempt.

Defendant urges that, as a matter of public policy, allowing this case to go to a jury would thwart Congress' intent to encourage the development of ground-breaking medical devices that operate to improve the health and longevity of the American people. Although Congress' desire to promote the development of medical technology was clearly expressed by the passage of the MDA, its legislative history indicates that "any fears regarding regulatory burdens were related more to the risk of *additional* federal and state regulation rather than the danger of preexisting duties under common law." *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2253. Moreover, any such concern was "far outweighed" by Congress' concern for the safety of those who use medical devices. *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2253.

Accordingly, we conclude that plaintiffs' common-law tort claims, based as they are upon general liability principles, are not preempted by the MDA.

IV

Plaintiffs' remaining claims, alleging breaches of express warranty and implied warranties of merchant-

ability and fitness, were not addressed by the *Medtronic* Court as to whether these types of claims were preempted by the MDA.

Breach of warranty claims, unlike the negligence and strict liability claims raised by plaintiffs, are not common-law tort actions, but are sanctioned by positive legislative enactments of state law. See 810 ILCS 5/2-313 (West 1994); 810 ILCS 5/2-314 (West 1994). They therefore present a different question than the one the *Medtronic* Court addressed.

We turn to plaintiffs' claim that defendant breached the implied warranties of merchantability and fitness. The FDA regulations specifically provide, as an example of a permissible general requirement, that the Uniform Commercial Code warranty of fitness is not preempted. 21 C.F.R. § 808.1(d)(1) (1995); *Medtronic*, 518 U.S. at ___, 116 S.Ct. at 2257. Because these state requirements are of "general applicability," and not "specifically developed 'with respect to' medical devices," they do not fall within the purview of section 360k. We conclude that these claims are not preempted by the MDA.

Concerning the breach of express warranty claims, plaintiffs allege that defendant marketed its product with the express warranty that the CVS catheters were fit for the purpose intended, were of marketable quality and free from defects, and would not injure the fetuses of pregnant women.

Our review of this question begins with the Supreme Court's decision in *Cipollone*. There, plaintiff brought numerous claims, including one alleging breach of express warranty, against a cigarette manufacturer based on certain statements in its advertisements made to his

deceased mother. *Cipollone*, 505 U.S. at 508, 112 S.Ct. at 2613, 120 L.Ed.2d at 418. Federal law required that all cigarette packages contain a health warning, and a federal preemption provision precluded states from imposing a requirement with respect to the advertising of cigarettes whose packages provided the mandated federal warning. The *Cipollone* plurality concluded the manufacturer's express warranty that smoking did not "present any significant health consequences" was not preempted by the federal provision because the warranty was a "contractual commitment voluntarily undertaken" by the cigarette manufacturer. *Cipollone*, 505 U.S. at 525-26, 112 S.Ct. at 2622, 120 L.Ed.2d at 428-29. The plurality reasoned that "[a] manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the 'requirements' imposed by an express warranty claim are not 'imposed under State law,' but rather *imposed by the warrantor*." (Emphasis in original.) *Cipollone*, 505 U.S. at 525, 112 S.Ct. at 2622, 120 L.Ed.2d at 428.

In the context of the MDA, previously there was a split of authority in the federal courts with regard to whether a breach of express warranty claim was preempted. Compare *Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39, 42 (6th Cir.1995), cert. granted and judgment vacated by, 518 U.S. ___, 116 S.Ct. 2576, 135 L.Ed.2d 1091 (1996), and *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 400-01 (4th Cir.1995), cert. granted and judgment vacated by, 518 U.S. ___, 116 S.Ct. 2575, 135 L.Ed. 2d 1090 (1996) (preemption) with *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1327 (3d Cir.1995), and *Kennedy*, 67 F.3d at 1459-60 (no preemption). Courts concluding that ex-

press warranty claims were not preempted followed the lead in *Cipollone*. In *Michael v. Shiley*, the court stated:

> "Express warranties arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law. * * * The parties to a contract, not the state, define the substantive obligations of the contract and hence any express warranties. While the state provides for the enforcement of the parties' bargain, it does not define each party's duties." 46 F.3d at 1325.

Because the MDA preempted only state requirements having the force of law, not private agreements, express warranties were not preempted. *Shiley*, 46 F.3d at 1325. We concur.

Decisions holding that express warranty claims are preempted by the MDA were limited to facts involving express warranties based on FDA-mandated labeling, packaging, and advertising, not claims based on a manufacturer's voluntarily-made representations regarding its product. *Duvall*, 65 F.3d at 400-01. See also *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.1993) (opinion of Torruella, J.). In addition, the judgments in *Martin* and *Duvall* since have been vacated by the Supreme Court, as earlier noted. Accordingly, those cases no longer have the force of law.

In the present case, the assertions forming the bases of the breach of express warranty claims arise by defendant's own express representations, not by a state-imposed duty. Therefore, express warranties by a manufacturer are not state "requirements" and thus fall outside of the scope of section 360k.

From the foregoing, we conclude that none of plaintiffs' state-law claims are preempted by the MDA and the circuit courts erred in granting defendant's motions for summary judgment. Accordingly, the judgments of the circuit courts are reversed and the causes are remanded for further proceedings not inconsistent with this opinion.

Reversed and remanded.

DiVITO and BURKE, JJ., concur.

(Letterhead of)

ILLINOIS SUPREME COURT
JULEANN HORNYAK, CLERK
SUPREME COURT BUILDING
SPRINGFIELD, ILLINOIS 62701
(217) 782-2035

December 4, 1996

Mr. Jeffrey Singer
Segal, McCambridge, Singer & Mahoney. Ltd.
20 South Clark Street
Suite 700
Chicago, IL 60603

No. 82017 - Sarah Kernats, a Minor, etc., et al., respondents, v. Smith Industries Medical Systems, Inc., etc., petitioner. Leave to appeal, Appellate Court, First District.

The Supreme Court today DENIED the petition for leave to appeal in the above entitled cause.

The mandate of this Court will issue to the Appellate Court on December 26, 1996.

SUPREME COURT OF ILLINOIS
WEDNESDAY, DECEMBER 4, 1996

THE FOLLOWING CASES ON THE LEAVE TO APPEAL DOCKET WERE DISPOSED OF AS INDICATED:

No. 80359 People State of Illinois, respondent, v. Anthony Smith, petitioner. Leave to appeal, Appellate Court, First District. (1-93-3519, 1-93-3520)

Petition for leave to appeal denied.

No. 80632 People State of Illinois, respondent, v. Loren Ethridge, petitioner. Leave to appeal, Appellate Court, Fifth District. (5-94-0107)

Petition for leave to appeal denied.

No. 80768 People of the State of Illinois ex rel. Silvette Lemardo, etc., respondent, v. Yusuf Broachwala, petitioner. Leave to appeal, Appellate Court, First District. (1-92-0189)

Petition for leave to appeal denied.

No. 80908 People State of Illinois, respondent, v. Theresita Aprieto, petitioner. Leave to appeal, Appellate Court, First District. (1-94-3676)

Petitioner having failed to file a petition for leave to appeal within the time allowed by order, this cause is DISMISSED.

No. 80995 People State of Illinois, petitioner, v. Tyreese Tooles, respondent. Leave to appeal, Appellate Court, Third District. (3-94-0627)

PETITION FOR LEAVE TO APPEAL ALLOWED.

This case is consolidated with Case Nos. 80997 & 81002.

No. 80997 People State of Illinois, petitioner, v. William Farmer, respondent. Leave to appeal, Appellate Court, Third District. (3-94-0163, 3-94-0164, 3-94-0165)

PETITION FOR LEAVE TO APPEAL ALLOWED.

This case is consolidated with Case Nos. 80995 & 81002.

No. 82011 City of Chicago, respondent, v. American Federation of State, County and Municipal Employees, etc., petitioner. Leave to appeal, Appellate Court, First District. (1-95-2055)

Petition for leave to appeal denied.

No. 82012 People State of Illinois, respondent, v. Thomas Ross, petitioner. Leave to appeal, Appellate Court, First District. (1-94-1789)

Petition for leave to appeal denied.

No. 82014 People State of Illinois, respondent, v. George Marshall, etc., petitioner. Leave to appeal, Appellate Court, First District. (1-94-0914)

Petition for leave to appeal denied.

No. 82015 People State of Illinois, respondent, v. Jose Medrano, petitioner. Leave to appeal, Appellate Court, First District. (1-94-2069)

Petition for leave to appeal denied.

No. 82016 People State of Illinois, respondent, v. Danny McGhee, petitioner. Leave to appeal, Appellate Court, First District. (1-95-1717)

Petition for leave to appeal denied.

No. 82017 Sarah Kernats, a Minor, etc., et al., respondents, v. Smith Industries Medical Systems, Inc., etc., petitioner. Leave to appeal, Appellate Court, First District. (1-94-4386, 1-95-3128, 1-95-3129)

Petition for leave to appeal denied.

No. 82018 People State of Illinois, respondent, v. Donta Childs, petitioner. Leave to appeal Appellate Court, First District. (1-94-4405)

Petition for leave to appeal denied.

No. 82019 People State of Illinois, respondent, v. Clarence Lewis, Jr., petitioner. Leave to appeal, Appellate Court, First District. (1-94-1752)

Petition for leave to appeal denied.

No. 82020 People State of Illinois, respondent, v. Gamel Scharoubim, petitioner. Leave to appeal, Appellate Court, First District. (1-95-3126)

Petition for leave to appeal denied.

[November 17, 1994]

IN THE CIRCUIT COURT OF COOK COUNTY
COUNTY DEPARTMENT, LAW DIVISION

SARAH KERNATS, a minor, by CYNTHIA KERNATS, her mother and next friend, CYNTHIA KERNATS, individually, and ANDREW KERNATS,	)	
Plaintiffs,	)	
v.	)	No. 92 L 13573
HOWARD GRUNDY, M.D., et al.,	)	
Defendants.	)	

ORDER

This Cause comes upon defendant SMITHS INDUSTRIES MEDICAL SYSTEMS' motion for summary judgment, due notice given and the Court fully advised in the premises:

IT IS HEREBY ORDERED said motion for summary judgment is granted. This is a final and appealable order and there is no just cause to delay its enforcement or appeal.

ENTER:

/s/ Joseph N. Casciato
Judge

Dated: November 17, 1994

[Dated June 22, 1995]

**IN THE CIRCUIT COURT OF
COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION**

JOYCE OSHODI, Individually and as mother and next friend of KENNETH OSHODI, a minor,	)	
Plaintiffs,	)	
v.	)	94 L 7177
MICHAEL REESE HOSPITAL AND MEDICAL CENTER, et al.,	)	
Defendants.	)	

MEMORANDUM ORDER

1. Background

Plaintiff Joyce Oshodi alleges that she was injured and her son Kenneth suffered limb deformities as a result of chorionic villus sampling (CVS) genetic testing performed in 1986. Defendant Smiths Industries Medical Systems, Inc. (SIMS) designed and distributed the CVS catheter used in the testing. Defendant SIMS moves for summary judgment asserting that Plaintiff's claims against Defendant SIMS (as set forth in Counts XXII through XXIV of Plaintiff's First Amended Complaint) are preempted by the Medical Devices Amendments of 1976, 21 U.S.C. §§360c-3601 (MDA).

2. Issue

The resolution of this motion turns on the meaning of 21 U.S.C. §360k(a) which provides:

> [E]xcept as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The issue is whether this federal statute preempts Plaintiff's common law claims as set out in Counts XXII through XXIV of the First Amended Complaint.

3. Discussion

Plaintiff contends that this statutory language preempts inconsistent regulations and statutes but not common law claims. Under 21 U.S.C. §360k(a), States or political subdivisions of a state are prohibited from establishing any "requirement" which differs from or adds to any "requirement" imposed under the MDA for certain types of medical devices. The United States Supreme Court stated in *Cipollone Liggett Group, Inc.*, 112 S.Ct. 2608, 2620; 120 L.Ed.2d 407 (1992), that "[T]he phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules."

The Illinois Appellate Court, Second District, has recently addressed the term "requirement" in the context of §360k(a). Citing *Cipollone* and 21 C.F.R. §808.1(b), the Court held that the term "requirement" includes court decisions. *Kus v. Sherman Hospital*, 268 Ill.App.3d 771 (2nd Dist. 1995). The Court is aware that *Kus* conflicts with *Haudrich v. Howmedica, Inc.*, 267 Ill.App.3d 630 (5th Dist. 1994). The Court finds unpersuasive the reasoning in *Haudrich* which would avoid preemption by a strained and narrow interpretation of "requirement." The Court agrees with the *Kus* opinion that:

> Thus, States may not impose requirements differing from or adding to the FDA requirements which relate to the safety or effectiveness of the device in question. A State requirement may stem from any requirement established by a State, including statutes, regulations, ordinances, or court decisions. 21 C.F.R. §808.1(b) (1993); see also *San Diego Building Trades Council, Millmen's Union, Local 2020 v. Garmon* (1959), 359 U.S. 236, 247, 3 L.Ed.2d 775, 784, 79 S.Ct. 773, 780 ("regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy"). 268 Ill.App.3d at 777.

Plaintiff also argues that her claims are not preempted because the CVS catheter at issue had not received FDA approval at the time Plaintiff underwent the CVS procedure. Plaintiff is correct to the extent that the CVS catheter at issue had not yet received "pre-market approval." However, the device had already been granted an Investigational Device exemption (IDE). (See Exhibit

B to Motion for Summary Judgment, IDE Approval Letter dated September 19, 1984). As stated in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 1333 (7th Cir. 1992), "the FDA will not grant an investigational-device exemption unless it believes that the device has sufficient promise of being proved safe and effective to justify the risk of its being used on human beings." The Seventh Circuit stressed the important policy reason for preemption that "if experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer." *Id.* at 1334. Therefore, when a device has been granted an IDE, claims relating to safety and effectiveness of the device are preempted. *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3rd Cir. 1994); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir. 1992); *Covey v. Surgidev Corp.*, 815 F. Supp. 1089 (N.D.Ohio 1993); *Hunsaker v. Surgidev Corp.*, 818 F.Supp. 744 (M.D. Pa. 1992). Congress plainly did not want state interference to discourage development of such promising devices.

Plaintiff cites 21 U.S.C. §360k(a) and 21 C.F.R. §808.1(d) for the proposition that in order for the MDA to have preemptive effect, there must be regulations specifically pertaining to the device at issue. Since there are no such device-specific regulations for CVS catheters, Plaintiff reasons that there is no preemption of Plaintiff's claims. However, the rigorous procedural requirements of the IDE approval process constitute "specific requirements" within the meaning of §360k(a) and §808.1(d). See *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3rd Cir. 1994); *Slater v. Optical Radiation Corp.*, 961 F. 2d 1330

(7th Cir. 1992); *Covey v. Surgidev Corp.*, 815 F.Supp. 1089 (N.D.Ohio 1993); *Hunsaker v. Surgidev Corp.*, 818 F.Supp. 744 (M.D. Pa. 1992). There is nothing in the words of the statute that any "requirement" be substantive as to safety and effectiveness rather than procedural in nature. The Seventh Circuit rejected Plaintiff's argument as follows:

> The argument assumes that the only federal requirement that might relate to the safety or effectiveness of the design of a medical device would be an actual specification of that design. The preemption provision does not say this, and so cramped an interpretation would cripple the exemption for investigational devices. The FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. If there were a known safe and effective design, the device would no longer be experimental. The point of the experiment is to find out whether it is safe and effective. *Public Citizen Health Research Group v. FDA,* supra, 704 F.2d at 1283. In the experimental phase the appropriate regulations of safety and effectiveness are procedural rather than substantive ones. They do not specify the safe and effective design; they specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect. 961 F.2d at 1333.

Plaintiff requests additional time to gather discovery, including FDA files, to support her theory that SIMS gained FDA approval by misrepresentation. This request has no merit. This Court is not the proper forum in which to launch such an inquiry or review. The prospect

of such an inappropriate inquiry merely adds weight to SIMS' argument that Congress intended preemption in cases such as this.

Applying the foregoing reasoning and authority to the various Counts, the Court finds summary judgment is appropriate as to each. Count XXII alleges defective design and manufacture, inadequate warnings, and inadequate instructions. Under *Slater*, such claims, are preempted. Count XXIII alleges breach of express and implied warranties. As stated in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), express warranty claims could only arise out of the FDA-approved labeling and packaging. Since such claims effectively would impose additional or different requirements on the device's labeling and packaging, they are preempted. Similarly, implied warranty claims would also impose requirements beyond those imposed under the MDA. Therefore, the implied warranty claims are also preempted. Count XXIV alleges negligence, failure to warn and inadequate or negligent testing. Under *Slater*, such claims are preempted.

In summary, since all of Plaintiff's claims are preempted by the MDA, Defendant SIMS' motion for summary judgment is granted. The Court further finds that there is no just reason for delaying enforcement or appeal of this order.

This case is set for status as to the remaining parties on July 6, 1995 at 10:15 a.m.

June 22, 1995

/s/ Robert V. Boharic
Judge

[June 30, 1995]

IN THE CIRCUIT COURT OF COOK COUNTY
COUNTY DEPARTMENT, LAW DIVISION

MARY SUSAN WILLIAMS, as mother and next friend of JOHN CALVIN WILLIAMS, a minor,	)	
Plaintiff,	)	
v.	)	No. 93 L 015781
ALAN CADKIN, M.D., et al.,	)	
Defendants.	)	

ORDER

This cause comes upon motion of defendant SMITHS INDUSTRIES MEDICAL SYSTEMS, INC., due notice given, parties present thru counsel and the Court fully advised in the premises:

IT IS HEREBY ORDERED defendant SMITHS INDUSTRIES' motion for summary judgment is granted. There exists no just cause to delay enforcement of this final and appealable order nor its appeal.

ENTER:

/s/ Jennifer Duncan Brice
Judge

Dated: June 30, 1995